Remarks

I. Status of the Claims and Support for Amendments

Upon entry of the foregoing amendment, claims 1-10, 15, 16, 18-29, 31-34, 36-39 and 40-43 are pending in the application, with claim 1 being the independent claim. Claims 11-14, 17, 30 and 35 have been canceled without prejudice or disclaimer of the subject matter therein. Claims 1-7, 9, 15, 18, 20, 32 and 36 are sought to be amended to correct typographical errors, to depend only from claims drawn to elected subject matter and to more clearly define the claimed subject matter. Support for new claims 40-43 may be found at page 40, lines 20-25, for example. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

II. Draftsperson's Objections to the Drawings

Substitute Figures 18 and 19A and 19B are offered in order to comply with PTO 948, the Notice of Draftsperson's Patent Drawing Review, attached to Paper No. 5. The top and left margins for Figures 19A and 19B were deemed not acceptable. The figure legends for Figures 18, 19A and 19B were deemed to be poor. These deficiencies

have been corrected in the substitute figures. These corrections introduce no new matter. Applicants respectfully request withdrawal of this objection to the drawings.

III. Summary of the Office Action

In the Office Action dated June 17, 2002, the Examiner has made one objection to the Information Disclosure Statement, two objections to the specification, two objections to the claims and six rejections of the claims. Applicants respectfully offer the following remarks to overcome or traverse each element of these objections and rejections in the Office Action.

IV. Objection to the Information Disclosure Statement

Document AR6 of the Information Disclosure Statement has been objected to because the reference contains a hyperlink to a web page address. First, Applicants thank the Examiner for noting consideration of the reference. Second, Applicants disagree with the Examiner's assertion that a hyperlink is not permitted. A hyperlink is not permitted when it is part of the specification, however, a hyperlink for an electronic document that is listed on form PTO-1449 is permitted. *See* MPEP 608.01, section entitled "Hyperlinks and Other Forms of Browser-Executable Code in the Specification," paragraph 2.

Attached herewith is a copy of page 6 of Applicants' Information Disclosure Statement filed June 14, 2001. Applicants respectfully request that the Examiner place her initials next to the citation for document AR6 and return a copy of this page with the

next Official Action.

V. Objection to the Specification

The disclosure has been objected to because (1) the Brief Description of the Drawings does not make reference to each specific figure and (2) the city/state location of the American Type Culture Collection should be updated. The Brief Description of the Drawings, where appropriate, has been amended to reference each specific figure. The location of the American Type Culture Collection has been updated. Applicants respectfully request withdrawal of the two objections to the specification.

VI. Objection to the Claims

Claims 4 and 15 are objected to for typographical errors. The errors have been corrected as suggested by the Examiner. Applicants respectfully request withdrawal of the objections to the claims.

Claims 18, 20, 32 and 36 are objected to for being dependent on non-elected claims. Claims 18, 20, 32, and 36 have been amended to depend only from elected claims. Applicants respectfully request withdrawal of the objections to the claims.

VII. Rejections under 35 U.S.C. § 112

Claims 1-10, 15, 16, 18-29, 31-34 and 36-39 are rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. Applicants respectfully traverse the

rejection of the claims as amended.

A. The Rejection of Claim 1

Claim 1 has been amended to include a positive process step that clearly refers to the preamble of the claim. Applicants respectfully request withdrawal of the rejection of the claim.

B. The Rejection of Claims 2-4 and 9

Claims 2-4 and 9 are rejected for allegedly lacking clear antecedent basis. The claims have been amended in the manner suggested by the Examiner. Applicants respectfully request withdrawal of the rejection of the claims.

C. The Rejection of Claims 5-7

Claims 5-7 are rejected for allegedly being indefinite for the use of the phrase "and/or" in the claims. While Applicants believe the claims are clear, the claims have been amended to more conventionally define the claimed subject matter. Applicants respectfully request withdrawal of the rejection of the claims.

VIII. Rejections under 35 U.S.C. § 102

Claims 1-8, 10, 15, 16, 18, 19, 28, 29, 31-33 and 36 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by Miller *et al.* (U.S. Patent No.

5,773,279) as evidenced by Brock *et al.* (Biology of Microorganisms, Fourth Edition (1984), Prentice-Hall, Inc., page 257). Applicants respectfully traverse this rejection.

Miller *et al.* is alleged to disclose a method for producing a dry powdered culture medium comprising buffer salts that include monobasic potassium phosphate and dibasic sodium phosphate. Miller *et al.* is also alleged to disclose a method for cultivating a bacterial cell, a culture medium that comprises a lipid, packaging and sterilizing their medium and a kit comprising the medium. *See* Office Action, mailed June 17, 2002, at page 6. Brock *et al.* is offered for the proposition that buffering salts are "for the purpose of maintaining the correct pH for cell culture." *See* Office Action, mailed June 17, 2002, at page 6, lines 13-14.

Under 35 U.S.C. § 102, a claim can only be anticipated if every element in the claim is expressly or inherently disclosed in a single prior art reference. *See Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983), *cert. denied*, 465 U.S. 1026 (1984). The cited references do not expressly or inherently disclose every element of the claimed subject matter. The Examiner has correctly noted that "Miller *et al.* does not explicitly state that their medium is automatically pH-adjusting." *See* Office Action, mailed June 17, 2002, at page 6, lines 10-11. Brock *et al.* also does not disclose an automatically pH-adjusting dry powdered culture medium. Brock *et al.* merely discloses that buffers can be used to maintain relatively constant pH during microbial growth and that different buffers are suitable for different pH ranges. *See* Brock *et al.*, page 257, final paragraph. Neither Miller *et al.* nor Brock *et al.* disclose determination of the ratio of pH-opposing forms of buffer salts to automatically provide the desired final pH upon reconstitution of the culture medium powder, as is required by item (a) of claim 1, for

example. Clearly, since Miller *et al.* and Brock *et al.* do not expressly or inherently disclose the step of determination of the ratio of pH-opposing forms of buffer salts to automatically provide the desired final pH upon reconstitution of the culture medium powder, these references cannot and do not anticipate the claims.

In view of the foregoing remarks, Applicants respectfully request that the rejections under 35 U.S.C. § 102(b) over Miller *et al.* and Brock *et al.* be reconsidered and withdrawn.

IX. Rejections under 35 U.S.C. § 103

A. The First Rejection under 35 U.S.C. § 103

Claims 20-27 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over Miller *et al.* (U.S. Patent No. 5,773,279) in view of GibcoBRL Product Catalogue and Reference Guide 1995-1996 (hereafter "GibcoBRL"). Applicants respectfully traverse this rejection.

Miller *et al.* is allegedly offered as a primary reference for the reasons summarized above in item VIII. Miller *et al.* is alleged to not specifically disclose cell culture media useful for culture of eukaryotic cells and cells lines derived therefrom. GibcoBRL is offered for the proposition that commercially available media for eukaryotic cells and cell lines were already known. The Examiner further states, without citation or support, that the "pH of these media preparations must be properly adjusted before the cells are added." *See* Office Action, mailed June 17, 2002, page 7, last three lines. The alleged motivation to combine the two references comes from the general

knowledge of one of ordinary skill in the art that the addition of the buffering salts from Miller *et al.* with the media disclosed in GibcoBRL eliminates a pH adjusting step that would result in the invention claimed in claims 20-27. *See* Office Action, at page 8, lines 5-9.

The Examiner has not established a *prima facie* case of obviousness because (1) there is no motivation in the cited art to combine Miller *et al.* with GibcoBRL, (2) Miller *et al.* is seriously deficient as a primary reference and (3) even if there was motivation to combine the two references, GibcoBRL does not cure the deficiencies in Miller *et al.* to arrive at the present invention.

The Examiner's contention that one of ordinary skill would have been motivated to have combined the disclosures of Miller *et al.* and GibcoBRL to arrive at the invention in claims 20-27 is not based on any statement in either of these references. In proceedings before the Patent and Trademark Office, the examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art. *See In re Piasecki*, 223 USPQ 785, 787-88 (Fed. Cir. 1984). The Examiner can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references in such a way as to produce the invention as claimed. *See In re Fine*, 5 USPQ2d 1596,1598 (Fed. Cir. 1988). Specifically, there must be a reason, suggestion, or motivation in the cited art that would motivate one of ordinary skill to combine the references, and that would also suggest a reasonable likelihood of success in making or using the invention as claimed as a result of that combination. *See In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988). Absent a motivation in the

cited art to combine the two references, Applicants respectfully assert that a *prima facie* case of obviousness has not been established.

Assuming, *arguendo*, that there was proper motivation in the art to combine Miller *et al.* with GibcoBRL, Miller *et al.* is seriously deficient as a primary reference. Rejected claims 20-27 depend from claim 16, and ultimately from claim 1. As discussed in item VIII above, Miller *et al.* does not expressly or inherently disclose a method for producing an automatically pH-adjusting dry powdered culture medium that includes determination of the ratio of pH-opposing forms of buffer salts to automatically provide the desired final pH upon reconstitution of the culture medium powder (claim 1). Therefore Miller *et al.* cannot anticipate or render obvious claims 20-27. Moreover, an obviousness rejection cannot be predicated upon a teaching alleged to be inherent in a prior art reference. *In re Spormann*, 150 U.S.P.Q. 449, 452 (CCPA 1966) ("That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown.").

The deficiencies in Miller *et al.* are not cured by the disclosure of GibcoBRL. GibcoBRL merely discloses various culture media and does not disclose an automatically pH-adjusting dry powdered culture media. Applicants note that media preparations by their nature contain pH buffers. Without buffers, e.g. buffering salts, pH cannot be properly controlled. Conventional laboratory technique requires pH adjustment with addition of a strong acid or a strong base to the buffered medium before cells are added. Neither Miller *et al.* nor GibcoBRL teaches or suggests the step of determination of the ratio of pH-opposing forms of buffer salts to automatically provide the desired final pH upon reconstitution of the culture medium powder. Hence, Miller *et al.* and GibcoBRL,

in combination, do not disclose or render obvious the invention of claims 20-27. Further, the skilled artisan would not have been motivated to combine the disclosures of Miller *et al.* and GibcoBRL to arrive at the present invention. Therefore, a *prima facie* case of obviousness has not been established.

In view of the foregoing remarks, Applicants respectfully request that the rejections under 35 U.S.C. § 103(a) over Miller *et al.* and in view of GibcoBRL be reconsidered and withdrawn.

B. The Second Rejection under 35 U.S.C. § 103

Claim 34 is rejected under 35 U.S.C. § 103 for allegedly being unpatentable over Miller *et al.* (U.S. Patent No. 5,773,279) in view of Chrisope *et al.* (U.S. Patent No. 5,155,039). Applicants respectfully traverse this rejection.

Miller *et al.* is allegedly offered as a primary reference for the reasons summarized above in item VIII. Miller *et al.* is alleged to not specifically disclose a composition comprising a dry powder medium and at least one cell. Chrisope *et al.* is alleged to disclose a kit comprising dried viable microorganisms in a vial.

The Examiner has not established a *prima facie* case of obviousness because (1) there is no motivation in the cited art to combine Miller *et al.* with Chrisope *et al.*, (2) Miller *et al.* is seriously deficient as a primary reference and (3) even if there was motivation to combine the two references, Chrisope *et al.* does not cure the deficiencies in Miller *et al.* to arrive at the present invention.

The Examiner's contention that one of ordinary skill would have been motivated to have combined the disclosures of Miller *et al.* and Chrisope *et al.* to arrive at the

invention in claim 34 is not based on any statement in either of these references. In proceedings before the Patent and Trademark Office, the examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art. *See In re Piasecki*, 223 USPQ 785, 787-88 (Fed. Cir. 1984). The Examiner can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references in such a way as to produce the invention as claimed. *See In re Fine*, 5 USPQ2d 1596,1598 (Fed. Cir. 1988). Specifically, there must be a reason, suggestion, or motivation in the cited art that would motivate one of ordinary skill to combine the references, and that would also suggest a reasonable likelihood of success in making or using the invention as claimed as a result of that combination. *See In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988). Absent a motivation in the cited art to combine the two references, Applicants respectfully assert that a *prima facie* case of obviousness has not been established.

Applicants reiterate and incorporate herein the remarks made above regarding the disclosure of Miller *et al.* As noted above, Miller *et al.* does not disclose a method for producing an automatically pH-adjusting dry powdered culture medium that includes determination of the ratio of pH-opposing forms of buffer salts to automatically provide the desired final pH upon reconstitution of the culture medium powder. As such, Miller *et al.* is seriously deficient as a primary reference. Moreover, an obviousness rejection cannot be predicated upon a teaching alleged to be inherent in a prior art reference. *In re Spormann*, 150 U.S.P.Q. 449, 452 (CCPA 1966) ("That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown.").

The deficiencies in Miller *et al.* are not cured by the disclosure of Chrisope *et al.* Chrisope *et al.* merely discloses a kit and method for preserving and storing dried, microbiological organisms for re-hydrating and delivering specific numbers of viable organisms and does not disclose an automatically pH-adjusting dry powdered culture media. *See* Abstract. Hence, Miller *et al.* and Chrisope *et al.*, in combination, do not disclose or render obvious the invention of claim 34. Further, the skilled artisan would not have been motivated to combine the disclosures of Miller *et al.* and Chrisope *et al.* to arrive at the present invention. Therefore, a *prima facie* case of obviousness has not been established.

In view of the foregoing remarks, Applicants respectfully request that the rejections under 35 U.S.C. § 103(a) over Miller *et al.* and in view of Chrisope *et al.* be reconsidered and withdrawn.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Robert W. Esmond

Robert W. Esmond
Attorney for Applicants
Registration No. 32,893

Date: Nov. 18, 2002

1100 New York Avenue, N.W., Suite 600
Washington, D.C. 20005-3934
(202) 371-2600

Version with markings to show changes made

In the Specification:

In the specification at page 11, line 2 to page 12, line 2, the Brief Description of the Drawings has been amended as follows:

[**Figure 1** is a histogram] **Figures 1A and 1B** are histograms of a densitometric scan of SDS-PAGE of samples of fetal bovine serum (FBS) prepared in powdered form by the methods of the invention (Figure 1A) and conventional liquid FBS (Figure 1B).

[**Figure 2** is a composite] **Figures 2A and 2B** are composites of line graphs of growth (Figure 2A) and passage success (Figure 2B) of SP2/0 cells in Dulbecco's Modified Eagle's Medium (DMEM) supplemented with 2% (w/v) FBS prepared in powdered form by the agglomeration methods of the invention.

[**Figure 3** is composite] **Figures 3A and 3B** are composites of histograms of spectrophotometric scans (λ = 200-350 nm) of powdered fetal bovine serum (FBS) prepared by spray-drying according to the methods of the invention (Figure 3A) or of standard liquid FBS (Figure 3B).

[**Figure 4** is a composite] **Figures 4A and 4B** are composites of line graphs showing the pH titration (buffer capacity), on two different dates (Figures 4A and 4B), of various dry powdered media (DPM) prepared by the methods of the invention or by ball-milling, with or without the addition of sodium bicarbonate.

[**Figure 5** is a composite] **Figures 5A and 5B** are composites of bar graphs showing the effect of agglomeration on dissolution rates (in water) of Opti-MEM I™

(Figure 5A) or DMEM (Figure 5B). Media were agglomerated with water or FBS as indicated.

[**Figure 6** is a composite] **Figures 6A and 6B** are composites of line graphs showing growth [over seven days]of SP2/0 cells in agglomerated Opti-MEM I™ (Figure 6A) or DMEM (Figure 6B), both containing 2% FBS.

[**Figure 7** is a composite] **Figures 7A, 7B and 7C** are composites of line graphs showing growth over seven days of SP2/0 cells (Figure 7A), AE-1 cells (Figure 7B) and L5.1 cells (Figure 7C) in agglomerated DMEM containing 10% FBS.

[**Figure 8** is a] **Figures 8A and 8B** are composites of line graphs showing passage success of SP2/0 cells in Opti-MEM I™ (Figure 8A) or DMEM (Figure 8B), agglomerated with either water or FBS, supplemented with 2% FBS.

[**Figure 9** is a composite] **Figures 9A, 9B and 9C** are composites of line graphs showing passage success of SP2/0 cells (Figure 9A), AE-1 cells (Figure 9B) and L5.1 cells (Figure 9C) in DMEM agglomerated with FBS and sodium bicarbonate and supplemented with 10% FBS.

In the specification at page 12, lines 10-17, the Brief Description of the Drawings has been amended as follows:

[**Figure 11** is a line graph] **Figures 11A and 11B** are line graphs of AE-1 cells cultured over six or seven days in medium containing 2% (▲) or 10% (◆) liquid fetal bovine serum (FBS), or 2% ( ) or 10% (■) powdered FBS prepared by the spray-drying methods of the invention. Duplicate experiments are shown in Figures 11A and 11B.

[**Figure 12** is a line graph] **Figures 12A and 12B** are line graphs of SP2/0 cells cultured over seven days in medium containing 2% (▲) or 10% (◆) liquid FBS, or 2% (✖) or 10% (■) powdered FBS prepared by the spray-drying methods of the invention. Duplicate experiments are shown in Figures 12A and 12B.

In the specification at page 12, line 25 to page 13, line 10, the Brief Description of the Drawings has been amended as follows:

[**Figure 16** is] **Figures 16A, 16B, 16C and 16D** are a series of line graphs indicating the effect of γ irradiation on the ability of transferrin to support the growth of 293 cells over four passages. In each graph, cells were cultured in standard serum-free 293 medium (◆), in medium without transferrin (■), in medium containing powdered transferrin that had been γ irradiated at -70°C (▲) or room temperature (✱), or in medium containing powdered transferrin that had not been γ irradiated but that had been stored at -70°C (✖) or at room temperature (●). Results for each data point are the averages of duplicate flasks.

Fig. 16A: passage 1 cells;

Fig. 16B: passage 2 cells;

Fig. 16C: passage 3 cells;

Fig. 16D: passage 4 cells.

[**Figure 17** is] **Figures 17A, 17B, 17C and 17D** are a series of bar graphs indicating the effect of γ irradiation, under different irradiation conditions, on the ability of FBS to support growth of anchorage-independent cells (Figures 17A and 17B) and

anchorage-dependent cells (Figures 17C and 17D) at first (Px1), second (Px2) and third (Px3) passages.

In the specification at page 13, lines 18-20, the Brief Description of the Drawings has been amended as follows:

[Figure 19 is] **Figures 19A and 19B** are a series of line graphs depicting the buffering kinetics for RPMI-1640 culture media in various forms, with or without the addition of $NaHCO_3$.

Please substitute the following paragraph for the pending paragraph beginning at page 41, line 15 and ending at page 42, line 5.

The reconstituted nutritive media, media supplements, media subgroups and buffers may be used to culture cells according to standard cell culture techniques which are well-known to one of ordinary skill in the art. In such techniques, the cells to be cultured are contacted with the reconstituted media, media supplement, media subgroup or buffer of the invention under conditions favoring the cultivation of the cells (such as controlled temperature, humidity, lighting and atmospheric conditions). Cells which are particularly amenable to cultivation by such methods include, but are not limited to, bacterial cells, yeast cells, plant cells and animal cells. Such bacterial cells, yeast cells, plant cells and animal cells are available commercially from known culture depositories, *e.g.*, American Type Culture Collection ([Rockville, Maryland] Manassas, Virginia),

Invitrogen ([La Jolla, California] Carlsbad, California) and others that will be familiar to one of ordinary skill in the art. Preferred animal cells for cultivation by these methods include, but are not limited to, insect cells (most preferably *Drosophila* cells, *Spodoptera* cells and *Trichoplusa* cells), nematode cells (most preferably *C. elegans* cells) and mammalian cells (including but not limited to CHO cells, COS cells, VERO cells, BHK cells, AE-1 cells, SP2/0 cells, L5.1 cells, hybridoma cells and most preferably human cells such as 293 cells, PER-C6 cells and HeLa cells), any of which may be a somatic cell, a germ cell, a normal cell, a diseased cell, a transformed cell, a mutant cell, a stem cell, a precursor cell or an embryonic cell, and any of which may be an anchorage-dependent or anchorage-independent (*i.e.*, "suspension") cell.

In the Claims:

Claims 11-14, 17, 30 and 35 are canceled without prejudice or disclaimer.

Claims 1-7, 9, 15, 18, 20, 32 and 36 are amended as follows:

1. (Once Amended) A method for producing an automatically pH-adjusting dry powdered culture medium, comprising:

(a) determining the ratio of pH-opposing forms of buffer salts required to be added to said powder to automatically provide a desired final pH upon reconstitution of said powder with a solvent; and

(b) adding amounts of pH-opposing forms of buffer salts to said powder in the ratio determined in step (a);

to produce an automatically pH-adjusting dry powdered culture medium having said desired final pH upon reconstitution.

2. (Once Amended) The method of claim 1, further comprising packaging said dry powdered culture medium.

3. (Once Amended) The method of claim 1, further comprising sterilizing said dry powdered culture medium.

4. (Once Amended) The method of claim 3, wherein said sterilization is accomplished by irradiating said dry powdered culture medium with gamma rays until said medium is sterile.

5. (Once Amended) The method of any one of claims 1-3, wherein said medium comprises at least one [monobasic and/or dibasic] buffering salt selected from the group consisting of a monobasic buffering salt and a dibasic buffering salt.

6. (Once Amended) The method of claim 5, wherein said monobasic buffering salt is a monobasic phosphate salt and said [and/or] dibasic buffering salt is a [monobasic and/or] dibasic phosphate salt.

7. (Once Amended) The method of claim 6, wherein [at least one of] said monobasic phosphate salt is a monobasic sodium phosphate salt and said [and/or] dibasic phosphate [salts] salt is a dibasic sodium phosphate salt.

9. (Once Amended) The method of claim 1, wherein said dry powder culture medium contains sodium bicarbonate but does not liberate CO_2 upon storage.

15. (Once Amended) A method of cultivating a cell comprising preparing an automatically pH-adjusting dry powdered culture medium prepared according to the method of any one of claims 1-3 and 9, reconstituting the medium with at least one solvent to form a culture medium solution, and contacting a cell with said solution under conditions favoring cultivation of the cell.

18. (Once Amended) The method of [any one of claims] claim [14,] 16[and 17], wherein said cell is a bacterial cell.

20. (Once Amended) The method of [any one of claims] claim [14,] 16[and 17], wherein said cell is a eukaryotic cell.

32. (Once Amended) The kit of claim 29[or claim 30], wherein said kit further comprises one or more additional containers containing at least one additional component selected from the group consisting of at least one growth factor, at least one culture medium supplement, at least one animal tissue extract, at least one animal organ

extract, at least one animal gland extract, at least one enzyme, at least one protein, at least one vitamin, at least one cytokine, at least one lipid, at least one trace element, at least one extracellular matrix component, at least one buffer, at least one antibiotic, and at least one viral inhibitor.

36. (Once Amended) The composition of claim 33[or claim 35], wherein said cell is selected from the group consisting of a bacterial cell, a yeast cell, a plant cell and an animal cell.

Claims 40-43 are sought to be added.